IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

G.A. Demopulos et al.

Attorney Docket No.: OMER-1-17356

Application No.: 09/839,633

Group Art Unit: 1614

Filed:

April 20, 2001

Examiner: Jarvis, W.

Title:

AND INFLAMMATION

IRRIGATION SOLUTION AND METHOD FOR INHIBITION OF PAIN

TRANSMITTAL LETTER

Seattle, Washington 98101

February 22, 2002

TO THE COMMISSIONER FOR PATENTS:

Information Disclosure Statement Transmittal A.

Transmitted herewith is an information disclosure statement, a citation of information, and 45 references in the above-identified application.

Respectfully Submitted,

OMEROS MEDICAL SYSTEMS, INC.

Marcia S. Kelbon

Vice President, Patent and General Counsel

Registration No. 34,358

Direct Dial No. 206.676.5020

I hereby certify that this correspondence is being hand delivered to the Commissioner for Patents, Washington, D.C. 20231, attention Examiner William Jarvis, Group Art Unit 1600 on the below date.

Person completing Deliver

jdg

OMEROS MEDICAL SYSTEMS, INC. 1420 Fifth Avenue Suite 2675 Seattle, Washington 98101 206.623.4688

-1-

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: G.A. Demopulos et al.

Attorney Docket No: OMER-1-17356

Application No.: 09/839,633

Group Art Unit: 1614

Filed:

April 20, 2001

Examiner: W. Jarvis

Title:

IRRIGATION SOLUTION AND METHOD FOR INHIBITION OF PAIN

AND INFLAMMATION

...

INFORMATION DISCLOSURE STATEMENT

Seattle, Washington 98101

February 22, 2002

22 PH 1:07

- ----

TO THE COMMISSIONER FOR PATENTS:

Applicants are aware of the information listed in the attached form that may be material to the prosecution of the above-identified patent application.

1. X Copies of the references listed as U13, U25, U136, U158, U167 - U209, U274 – U289, F15, F29 - F95, O157, and O244 - O849 are submitted herewith. Copies of the remaining listed patents, publications, and other information were previously cited by or submitted to the Patent and Trademark Office in prior Application No.s 09/072,913, filed May 4, 1998 and 08/670,699 filed June 26, 1996, and relied upon for an earlier filing date under 35 U.S.C. § 120. It is noted for the Examiner's convenience that the disclosure of each of the cited US Patents to Demopulos et al. is identical, and are cited because of the differing claims.

OMEROS MEDICAL SYSTEMS, INC. 1420 Fifth Avenue Suite 2675 Seattle, Washington 98101 206.623.46898101 206.682.8100 2. X Pursuant to 37 C.F.R. § 1.97(b), this Information Disclosure Statement is being filed within three months of the filing date of the national application (other than a CPA), within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, before the mailing date of a first Office Action on the merits, or before the mailing date of a first Office Action after the filing of an RCE.

Respectfully submitted,

OMEROS MEDICAL SYSTEMS, INC.

Marcia S. Kelbon

Vice President, Patent and General Counsel

Registration No. 34,358 Direct Dial No. 206.676,5020

I hereby certify that this correspondence is being hand delivered to the Commissioner for Patents, Washington, D.C. 20231, attention Examiner William Jarvis, Group Art Unit 1600 on the below date.

Date: 2/22/02

Person completing Delivery:

OMEROS MEDICAL SYSTEMS, INC. 1420 Fifth Avenue Suite 2675 Seattle, Washington 98101 206.623.4688

MSK:jdg

INFORMATION CITED BY APPLICANTS THAT MAY BE MATERIAL TO THE PROSECUTION OF THE SUBJECT APPLICATION

Applicants: G.A. Demopulos et al.

Attorney Docket No: OMER-1-17356 €

Serial No:

09/839,633

Group Art Unit: 1614

Filed:

April 20, 2001

Examiner: W. Jarvis

2 P

Title:

IRRIGATION SOLUTION AND METHOD FOR INHIBITION OF PAIN A

INFLAMMATION

U.S. PATENT DOCUMENTS

| *Examiner | | Document No. | | |
|-----------|-----|--------------|------------|----------------------|
| Initial | ID | | Date | Name |
| | U1 | 4,504,493 | 03/12/1985 | Marshall et al. |
| | U5 | 5,051,443 | 09/24/1991 | Neufeld et al. |
| | U6 | 5,272,139 | 12/21/1993 | Cary |
| | U11 | 4,872,865 | 10/10/1989 | Bloebaum et al. |
| | U13 | 4,971,955 | 11/1990 | Soll et al. |
| | U14 | 4,938,970 | 07/1990 | Hustead et al. |
| | U16 | 5,304,724 | 04/19/1999 | Newton, W. |
| | U19 | 5,411,743 | 05/02/1995 | Moore et al. |
| | U20 | 5,350,761 | 09/27/1994 | Van Duzer et al. |
| | U24 | 5,288,725 | 02/22/1994 | Witherup et al. |
| | U25 | 4,640,912 | 02/03/1987 | Hausman, M. |
| | U28 | 5,536,241 | 07/16/1996 | Zapol, W. |
| | U29 | 5,512,055 | 04/30/1996 | Domb et al. |
| | U44 | 4,490,379 | 12/25/1984 | Podos et al. |
| | U45 | 4,525,359 | 06/25/1985 | Greenway, III et al. |
| | U56 | 4,880,791 | 11/14/1989 | Weithmann et al. |
| | U61 | 5,502,080 | 05/26/1996 | Hitzig |
| | U62 | 5,618,563 | 04/08/1997 | Berde et al. |
| | U63 | 5,658,955 | 08/19/1997 | Hitzig |
| | U70 | 5,744,482 | 04/28/1998 | Cohen et al. |
| | U71 | 5,468,505 | 11/21/1995 | Hubbell et al. |
| | | | | |

| U79 | 4,659,714 | 04/21/1987 | Watt-Smith |
|----------|--------------|------------|------------------|
| U136 | 5,605,690 | 02/25/1997 | Jacobs et al. |
| U158 | 5,616,688 | 04/1997 | Cerami et al. |
| U164 | 5,800,385 | 09/01/1998 | Demopulos et al. |
| U165 | 5,820,583 | 10/13/1998 | Demopulos et al. |
| U167 | 5,767,064 | 06/16/1998 | Sims et al. |
| U188 | 5,319,071 | 06/07/1994 | Dower et al. |
| U189 | 5,726,148 | 03/10/1998 | Katoh et al. |
| U190 | 5,817,306 | 10/06/1998 | Haskill et al. |
| U191 | 5,447,851 | 09/05/1995 | Beutler et al. |
| U209 | 5,942,241 | 8/24/1999 | Chasin et al. |
| U272 | 5,858,017 | 01/12/1999 | Demopulos et al |
| U273 | 5,860,950 | 01/19/1999 | Demopulos et al |
| U274 | 6,210,394 | 04/03/2001 | Demopulos et al |
| U275 | 6,242,447 B1 | 06/05/2001 | Demopulos et al |
| U276 | 6,254,585 B1 | 07/03/2001 | Demopulos et al |
| U277 | 6,261,279 B1 | 07/17/2001 | Demopulos et al |
| U278 | 6,056,715 | 05/02/2000 | Demopulos et al |
| U280 | 5,610,184 | 3/11/1997 | Shahinian, Jr. |
| U282 | 5,480,901 | 1/2/1996 | Baker et al. |
| U284 | 6,306,820 | 10/23/2001 | Bendele et al. |
| U285 | 5,180,812 | 01/19/1993 | Dower et al. |
| U286 | 5,766,585 | 06/16/1998 | Evans et al. |
| U287 | 5,767,065 | 06/16/1998 | Mosley et al. |
| U288 | 5,449,756 | 09/12/1995 | Taniguchi et al. |
| U289 | 5,578,707 | 11/26/1996 | Norick et al. |

FOREIGN PATENT DOCUMENTS

| *Examiner | | Document No. | Publication Date | | Translation |
|-----------|-----|-----------------|------------------|----------|-------------|
| Initial | ID | | | Country | Provided |
| | | | | | Yes No |
| | F1 | WO 95/16435 | 06/22/1995 | PCT | X |
| | F2 | EP 0,364,266 A2 | 04/18/1990 | European | X |
| | F7 | WO 92/04008 | 03/19/1992 | PCT | X |
| | F8 | EP 0,351,755 | 01/24/1990 | European | X |
| | F9 | WO 95/27482 | 10/19/1995 | PCT | X |
| | F10 | WO 91/04058 | 04/04/1991 | PCT | X |
| | F15 | WO 94/06476 | 03/31/1994 | PCT | X |
| | F16 | WO 96/29074 | 09/26/1996 | European | X |
| | F29 | WO 96/26738 | 09/06/1996 | PCT | X |
| | F61 | WO 95/25795 | 09/28/1995 | PCT | X |
| | F62 | WO 96/17869 | 06/13/1996 | PCT | X |
| | F63 | EP 0,623,674 A1 | 11/09/1994 | European | X |
| | F82 | WO 97/24459 | 07/10/1997 | PCT | X |
| | F83 | EP 0,715,855 A2 | 06/12/1996 | European | X |
| | F84 | EP 0,710,479 B1 | 01/07/1999 | European | X |
| | F85 | WO 96/34599 | 11/07/1996 | PCT | X |
| | F86 | WO 98/24477 A1 | 06/11/1998 | PCT | X |
| | F87 | WO 01/87328 A2 | 11/22/2001 | PCT | X |
| | F88 | WO 00/62790 | 10/26/2000 | PCT | X |
| | F95 | WO 00/36108 | 06/22/2000 | PCT | X |

OTHER INFORMATION (Including Author, Title, Date, Pertinent Pages, Etc.)

| *Examiner Initial | ID | Document Information |
|----------------------|-----|--|
| | O01 | Thulesius, O., et al., "Ketanserin in intermittent claudication: effect on walking distance, blood pressure, and cardiovascular complications," <i>J. Cardiovasc. Pharmacol.</i> 9: 728-733 (1987). |
| | O02 | Hedner, T., et al., "Effects of a new serotonin antagonist, ketanserin, in experimental and clinical hypertension," <i>Am. J. Hypertens.</i> 1:317S-323S (1988). |
| | O03 | Hof, R.P., et al., "Antiarrhythmic and hemodynamic effects of tropisetron in anesthetized rabbits," <i>J. Cardiovasc. Pharmacol.</i> 22:499-505 (1993). |

| O05 | Naesh, O., et al., "Platelet activation in mental stress," Clin. Physiol. 13:299-307 (1993). |
|---------|--|
| O06 | Evans, R.G., et al., "Effects of 5-HT-receptor and alpha 2-androceptor ligands on the haemodynamic response to acute central hypovolemia in conscious rabbits," <i>Br. J. Pharmacol.</i> 109: 37-47 (1993). |
| O07 | Van Hemelrijck, J., et al., "Blood pressure management during aortic surgery: urapidil compared to isosorbide dinitrate," <i>J. Cardiothorac. Vasc. Anesth.</i> 7:273-278 (1993). |
| O08 | Evans, R.G., et al., "A CNS serotonergic mechanism in acute central hypovolemia in conscious rabbits?" <i>J. Cardiovasc. Pharmacol.</i> 19: 1009-1017 (1992). |
| O10 | Vyssoulis, G.P., et al., "Left ventricular hypertrophy regression and function changes with ketanserin in elderly hypertensives," <i>Cardiovasc. Drugs Ther.</i> 4 :81-84 (1990). |
| 011 | Sigal, S.L., et al., "Effects of Serotonin-Receptor Blockade on Angioplasty-Induced Vasospasm in an Atherosclerotic Rabbit Model," Arterioscler. Thrombosis 11:770-783 (1991). |
| O12 | Kalsner, S., et al., "Coronary arteries of cardiac patients are hyperreactive and contain stores of amines: a mechanism for coronary spasm," <i>Science</i> 223:1435-1437 (1984). |
| O13 | Willerson, J.T., et al., "Specific Platelet mediators and unstable coronary artery lesions," <i>Circulation</i> 80: 198-205 (1989). |
| O14 | Saxena, P.R., et al., "Cardiovascular effects on serotonin agonists and antagonists," <i>J. Cardiovasc. Pharmacol.</i> 15 :S17-S34 (1990). |
| O16 | Ashton, J.H., et al., "Serotonin as a mediator of cyclic flow variations in stenosed canine coronary arteries," <i>Circulation</i> 73: 572-578 (1986). |
| 017 | Douglas, W.W. "Histamine and 5-hydroxytryptamine (serotonin) and their antagonists," In: <i>The Pharmacological Basis of Therapeutics</i> 605-638 (1985). |
| O20 | Kessler, W., et al., "Excitation of cutaneous afferent nerve endings in vitro by a combination of inflammatory mediators and conditioning effect of substance P," Exp. Brain Res. 91:467-476 (1992). |
| O22 | Lang, E., et al., "Chemosensitivity of fine afferents from rat skin in vitro," <i>J. Neurophysiol.</i> 63 :887-901 (1990). |

| O23 | Levine, J.D., et al., "Desipramine enhances opiate postoperative analgesia," <i>Pain</i> 27:45-49 (1986). |
|---------|--|
| O25 | Richardson, B.P., et al., "Identification of serotonin M-receptor subtypes and their specific blockade by a new class of drugs," <i>Nature</i> 316: 126-131 (1985). |
| O26 | Ringkamp, M., et al., "Activated human platelets in plasma excite nociceptors in rat skin, in vitro," <i>Neurosci. Lett.</i> 170: 103-106 (1994). |
| O32 | Buzzi, M.G., et al., "The antimigraine drug, sumatriptan (GR43175), selectively blocks neurogenic plasma extravasation from blood vessels in dura mater," <i>Br. J. Pharmacol.</i> 99 :202-206 (1990). |
| O33 | Buzzi, M.G., et al., "5-Hydroxytryptamine receptor agonists for the abortive treatment of vascular headaches block mast cell, endothelial and platelet activation within the rat dura mater after trigeminal stimulation," <i>Brain Res.</i> 583:137-149 (1992). |
| O34 | Zochodne, D.W., et al., "Sumatriptan blocks neurogenic inflammation in the peripheral nerve trunk," <i>Neurology</i> 44: 161-163 (1994). |
| O37 | Schwartz, M.M., et al., "Vascular leakage in the kidney and lower urinary tract: effects of histamine, serotonin and bradykinin," <i>Proc. Soc. Exp. Biol. Med.</i> 140 :535-539 (1972). |
| O38 | Holliman, C.J., et al., "The effect of ketanserin, a specific serotonin antagonist, on burn shock hemodynamic parameters in a porcine burn model," <i>J. Trauma</i> 23:867-871 (1983). |
| O39 | Serruys, P.W., et al., "Evaluation of ketanserin in the prevention of restenosis after percutaneous transluminal coronary angioplasty; a multicenter randomized double-blind placebo-controlled trial," Circulation 88:1588-1601 (1993). |
| O40 | Cohen, B.M., et al., "Intracoronary cocktail infusion during rotational ablation: safety and efficacy," <i>Transcatheter Cardiovascular Therapeutics</i> (1995). |
| O43 | Berkenboom, G., et al., "Atherosclerosis and responses of human isolated coronary arteries to endothelium-dependent and -independent vasodilators," <i>J. Cardiovasc. Pharmacol.</i> 14:S35-S39 (1989). |
| O44 | Kaumann, A.J., et al., "Variable participation of 2HT1-like receptors and 5-HT1 receptors in serotonin-induced contraction of human isolated coronary arteries," <i>Circulation</i> 90 :1141-1153 (1994). |

| O45 | Quast, U., et al., "Cellular Pharmacology of Potassium Channel Openers in Vascular Smooth Muscle," <i>Cardiovascular Research</i> 28 :805-810 (1994). |
|----------|--|
| O86 | Golino, P., et al., "Failure of nitroglycerine and diltiazem to reduce platelet-mediated vasoconstriction in dogs with coronary artery stenosis and endothelial injury: further evidence for thromboxane A ₂ and serotonin as mediators of coronary artery vasoconstriction in vivo," <i>J. Am. Coll. Cardiol.</i> 15 :718-726 (1990). |
| O89 | DeCaterina, R., et al., "A Double-blind, Placebo-controlled Study of Ketanserin in Patients with Prinzmetal's Angina," <i>Circulation</i> 69:889-894 (1984). |
| O90 | Golino, P., et al., "Divergent Effects of Serotonin on Coronary-Artery Dimensions and Blood Flow in Patients with Coronary Artherosclerosis and Control Patients," <i>New Engl. J. Med.</i> 324 :641-648 (1991). |
| O91 | Golino, P., et al., "Local Effect of Serotonin Released During Coronary Angioplasty," New Engl. J. Med. 330:523-528 (1994). |
| O93 | Ashton, J.H., et al., "Serotonin S ₂ and Thromboxane A ₂ -Prostaglandid H ₂ Receptor Blockade Provide Protection Against Epinephrine-Induced Cyclic Flow Variations in Severly Narrowed Canine Coronary Arteries," <i>J. Am. Coll. Cardiol.</i> 13: 755-763 (1989). |
| O94 | Yao, S., et al., "Combined ADP and Thromboxane A ₂ Antagonism Prevents Cyclic Flow Variations is Stenosed and Endothelium-Injured Arteries in Nonhuman Primates," <i>Circulation</i> 88:2888-2893 (1993). |
| O116 | Cohen, B.M., et al., "Cocktail attenuation of rotational ablation flow effects (CARAFE) study: pilot," <i>Cathet. Cardiovasc. Diagn.</i> Suppl. 3 :69-72 (1996). |
| O133 | Sosnowski, M., et al., "Spinal Administration of Receptor-Selective Drugs as Analgesics: New Horizons," <i>J. Pain Symptom Manag.</i> 5:204-213 (1990). |
| O157 | Thomas, et al., "The Direct Perfusion of Surgical Wounds with Local Anaesthetic Solution: An Approach to Postoperative Pain?," <i>Annal R Coll Surg</i> 65 :226-229 (1983). |
| O160 | Kuga, T., et al., "Inhibitory Effects of Aspirin on Coronary Hyperreactivity to Autacoids After Arterial Balloon Injury in Minature Pigs," <i>J. Cardiovasc. Pharmacol.</i> 25 :273-281 (1995). |

| O175 | Reifart, et al., "Randomized Comparison of Angioplasty of Complex Coronary Lesions at a Single Cetner," Circulation 96:91-98 (1997). |
|----------|---|
| O178 | Willerson, J.T., et al., "Pretreatment with Antagonists to Thromboxane A2, Serotonin and ADP Reduces Neointimal Proliferation in Canine Coronary Arteries after Endothelial Injury," <i>J. Am. Coll. Cardiol.</i> Incomplete Data :906-32(1994). |
| O180 | Knorr, A.M. "Why is Nisoldipine a Specific Agent in Ischemic Left Ventricular Dysfunction?" Am. J. Cardiol. 75:36E-40E (1995). |
| O181 | Pierce, P.A., et al., "Dual Effect of the Serotonin Agonist, Sumatriptan, on Peripheral Neurogenic Inflammation," <i>Reg. Anesth.</i> 21:219-225 (1996). |
| O183 | Herrman et al., "Pharmacological Approaches to the Prevention of Restenosis Following Angioplasty," <i>Drugs</i> 46: 18-52 (1993). |
| O184 | Vahanian et al., "Role of Calcium Channel Blockers in Reducing Acute Ischemia and Preventing Restenosis in PCTA," <i>Drugs</i> 52: 9-15 (1996). |
| O185 | Narayanan et al., "Recombinant Hirudin: Initial Observations in Reconstructive Microsurgery," <i>Haemostasis</i> 21:168-171 (1991). |
| O186 | el-Sanadiki, M.N., et al., "Reduction of Intimal Hyperplasia and Enhanced Reactivity of Experimental Vein Bypass Grafts with Verapamil Treatment," <i>Ann. Surg.</i> 212:87-96 (1990). |
| O195 | Blackham et al., "FPL 62064 a Topically Active 5- Lipoxygenase/Cycloxygenase Inhibitor," Agents and Actions 30:432- 442. |
| O196 | Hirayama et al., "NK, Receptors Mediate Tachykinin-Induced Plasma Extravasation in the Rat Knee," Agents Actions 40:171-175 (1994). |
| O244 | Klein, J.A., "The Tumescent Technique Anesthesia and Modified Liposuction Technique," <i>Dermatologic Clinics</i> 8:425-437 (1990). |
| O246 | Ostad et al., "Tumescent Anesthesia with a Lidocaine Dose of 55 mg/kg is Safe for Liposuction" <i>Dermatol Surg</i> 22: 921-927 (1996). |
| O341 | Moreland, et al., "Treatment Of Rheumatoid Arthritis With A Recombinant Human Tumor Necrosis Factor Receptor (P75)-Fc Fusion Protein [See Comments]," N Engl J Med 337:141-147 (1997). |

| Examiner | | |
|----------|------|--|
| | O849 | Karczag, et al., "Mouse Peritoneal Cells Activated With a Combination of Indomethacin, Poly I: C and Syncumar Inhibit the Take of Lewis Lung Carcinoma, in Adoptive Transfer Assay," Acta Microbiologia Hung 34:207-214 (1987). |
| | O848 | Jacobi, et al., "Inhibition of Peritoneal Tumor Cell Growth and Implantation in Laparoscopic Surgery in a Rat Model," <i>Am J Surg</i> 174:359-363 (1997). |
| | O843 | Ettehadi et al., "Elevated Tumour Necrosis Factor-Alpha (TNF-Alpha) Biological Activity In Psoriatic Skin Lesions," Clin Exp Immuno 96:146-151 (1994) |
| | O609 | Mohler et al., "Soluble Tumor Necrosis Factor (TNF) Receptors Are Effective Therapeutic Agents In Lethal Endotoxemia And Function Simultaneously As Both TNF Carriers And TNF Antagonists," <i>J Immunol</i> 151:1548-1561 (1993). |
| | O342 | Moreland, et al., "Recombinant Soluble Tumor Necrosis Factor Receptor (P80) Fusion Protein: Toxicity And Dose Finding Trial In Refractory Rheumatoid Arthritis," <i>J Rheumatol</i> 23:1849-1855 (1996). |

*Examiner: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609; draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to applicant.

MSK:jdg